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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,213	08/10/2001	Srinivas Shankara	GA0197C	7369

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Deborah A. Dugan, Genzyme Corporation
15 Pleasant Street Connector
P.O. Box 9322
Framingham, MA 01701-9322

EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,213	SHANKARA, SRINIVAS	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,11-29 and 32-43* is/are pending in the application.

4a) Of the above claim(s) *2,7,11-22,27,28 and 35-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,23-26,29,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group I without traverse and species election of a recombinant polynucleotide comprising a first specific antigenic gene encoding a viral antigen without the presence of other elements and dendritic cells transfected with the recombinant polynucleotide is acknowledged. It is noted that the claims drawn to the species of a polynucleotide encoding a bacterial antigen will be included in this Office action for examination since no serious burden is imposed on the Office. Accordingly, claims 1, 3, 23-26, 29, 32, and 34 read on the elected invention, and claims 2, 7, 11-22, 27, 28, and 35-43 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

Claims 1, 3, 23-26, 29, 32, and 34 are under current examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 23-26, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by *Astori et al* (Mol Immunol 1996;33:1017-24).

Astori et al teach a recombinant polynucleotide (plasmid pET/S-$P30_4$, fig. 1, a gene delivery vehicle) comprising a polynucleotide encoding four tetanus toxin T-helper epitopes P30 (antigenic peptides) operably linked to each other, wherein the polypeptide is a fragment of a pathogenic antigen of tetanus bacteria. *Aston et al* also teach transfecting *E. coli* (host cells) with the recombinant polynucleotide. Thus, *Aston et al* anticipate instant claims.

Claims 1, 3, 23-26, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by *Ferrari et al* (US 5,243,038).

Ferrari et al teach a recombinant polynucleotide (e.g. fig. 3, a plasmid gene delivery vehicle) comprising a polynucleotide encoding repetitive peptides (column 3, line 45), wherein the coded peptides repeat at least twice, and can go up to twenty (ten different A's, A=2) repeats (column 3, lines 45-58). *Ferrari et al* go on to teach that the peptides could be surface antigens of disease-causing microorganisms, such as bacteria and viruses (column 10, lines 16-21). *Ferrari et al* also teach transfecting *E coli* or *B. subtilis* (prokaryotic host cells) with the recombinant polynucleotide (column 12). Thus, *Ferrari et al* anticipate instant claims.

Claims 1, 3, 23-26, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by *Michel et al* (US 5,648,241).

Michel et al teach a polynucleotide encoding nine identical 246-nucleotide tandem repeating units of alpha antigen from bacteria streptococcal proteins (column

34, lines 15-32), wherein the polynucleotide was cloned to a plasmid gene delivery vehicle pJMS23 and expressed in *E coli* (prokaryotic host cells, (column 35, lines 45-47). Thus, *Michel et al* anticipate instant claims.

Claims 1, 3, 23-26, 29, 32 are rejected under 35 U.S.C. 102(a) as being anticipated by *WO 99/35260.*

WO 99/35260 teaches a recombinant polynucleotide (e.g. mid-section in page 5) comprising a linear concatamer of DNA sequences encoding a first polypeptide of at least 30 amino acids (abstract), wherein the polypeptide could be an immunogen, preferably an antigenic protein from pathogenic bacteria and viruses, e.g. hepatitis B surface antigen and meningococcal surface proteins (2nd paragraph, page 4). *WO 99/35260* also teaches transfecting prokaryotic, eukayotic, and mammalian host cells with the recombinant polynucleotide (last paragraph, page 7). Thus, *WO 99/35260* anticipates instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 29, 32, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Astori et al* (Mol Immunol 1996;33:1017-24), or *Ferrari et al* (US 5,243,038), or *WO 99/35260,* in view of *Philip et al* (US 6,652,850).

As discussed in the immediate preceding section, *Astori et al, Ferrari et al, and WO 99/35260* teach a recombinant polynucleotide encoding and expressing a repetitive antigenic protein or a plurality of a first antigenic peptide operably linked to each other, wherein the peptide is obtained from pathogenic bacterial and viral antigens, wherein the polynucleotide could be used as an antigen for immunization (vaccination). *Astori et al*, and *WO 99/35260* teach multiple repeats of an antigen is highly immunogenic, and *Ferrari et al* teach that certain pathogenic antigens are in the form of repetitive peptides. But they did not teach manipulating dendritic cells with the polynucleotides.

Philip et al teach that many attempts have been made to elicit immune response in subjects in need, but the success is limited because the difficulty in presenting the desired antigens. They go on to teach that such could be overcome by manipulating dendritic cells, a well-known high potent antigen-presenting cell, with a nucleic acid encoding a specific antigen and using such to evoke a specific immune response, wherein the manipulation could be carried out *in vitro* or *in vivo* (e.g. column 3, lines 18-45), and wherein the antigen could be a pathogenic microbial antigen such as a viral antigen (e.g. abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Philip et al* by simply using the polynucleotide constructs as taught by *Astori et al, Ferrari et al, and WO 99/35260* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because a. certain pathogenic antigenic epitope has repeating sequences (*Ferrari et al*, column 10, lines 17-19), and b. multiple repeats of antigenic epitope are highly immunogenic (*Astori et al*, title, and *WO 99/35260*, page 4, 2nd paragraph). Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **703-308-0196**.

JANICE LI
PATENT EXAMINER

Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
January 22, 2004